



4164-01-P

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

**[Docket No. FDA-2018-D-4534]**

### **Reducing Microbial Food Safety Hazards in the Production of Seed for Sprouting: Draft Guidance for Industry; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for industry entitled "Reducing Microbial Food Safety Hazards in the Production of Seed for Sprouting." The draft guidance document, when finalized, will make the sprout seed industry (seed growers, conditioners, packers, holders, suppliers, and distributors) aware of FDA's serious concern with the continuing outbreaks of foodborne illness associated with the consumption of raw and lightly-cooked sprouts and provide FDA's recommendations to firms throughout the production chain of seed for sprouting.

**DATES:** Submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that FDA considers your comment on the draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance at any time as follows:

#### *Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2018-D-4534 for "Reducing Microbial Food Safety Hazards in the Production of Seed for Sprouting: Draft

Guidance for Industry." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the

prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Office of Food Safety, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance.

**FOR FURTHER INFORMATION CONTACT:** Patricia Homola, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1700.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

We are announcing the availability of a draft guidance for industry entitled "Reducing Microbial Food Safety Hazards in the Production of Seed for Sprouting." The draft guidance, when finalized, will make the sprout seed industry (seed growers, conditioners, packers, holders, suppliers, and distributors) aware of our serious concern with the continuing outbreaks of foodborne illness associated with the consumption of raw and lightly-cooked sprouts and provide our recommendations to firms throughout the production chain of seed for sprouting. In the development of the draft guidance, we considered three documents related to food safety and hygienic production of seed for sprouting: (1) the Codex Code of Hygienic Practice for Fresh Fruits and Vegetables Annex II, Annex for Sprout Production (Ref. 1); (2) the International Sprout Growers Association-Institute for Food Safety and Health's "U.S. Sprout Production Best

Practices" (Section 2. Raw Material Sourcing) (Ref. 2); and (3) the European Sprouted Seeds Association (ESSA) Hygiene Guideline for the Production of Sprouts and Seeds for Sprouting (Section 2. Production of Seeds) (Ref. 3). We have incorporated aspects of these documents that are consistent with our laws and regulations, as well as our existing policies.

We are issuing the draft guidance consistent with our good guidance practice regulation (21 CFR 10.115). The draft guidance, when finalized, will represent our current thinking on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternate approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

## II. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/FoodGuidances> or <https://www.regulations.gov>. Use the FDA website listed in the previous sentence to find the most current version of the guidance.

## III. References

The following references are on display at the Dockets Management Staff (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>. FDA has verified the website addresses, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

1. Codex "Code of Hygienic Practice for Fresh Fruits and Vegetables," CAC/RCP 53-2003, Annex II, Annex for Sprout Production, Revision 2010. Retrieved from [https://www.ifsh.iit.edu/sites/ifsh/files/departments/ssa/pdfs/codex2003\\_053e.pdf](https://www.ifsh.iit.edu/sites/ifsh/files/departments/ssa/pdfs/codex2003_053e.pdf).

2. International Sprout Growers Association-Institute for Food Safety and Health's "U.S. Sprout Production Best Practices" (Section 2. Raw Material Sourcing). Retrieved from <https://www.ifsh.iit.edu/us-sprout-industry-production-best-practices>.
3. Official Journal of the European Union, "ESSA Hygiene Guideline for the Production of Sprouts and Seeds for Sprouting (2017/(220/ 03)," (Section 2. Production of Seeds). Retrieved from [https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52017XX0708\(01\)&from=EN](https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52017XX0708(01)&from=EN)

**Dated:** June 19, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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